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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,309	08/03/2005	Stephane Miras	263270US0PCT	7343

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EXAMINER	
HAMIDINIA, SHAWN A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,309	MIRAS ET AL.	
	Examiner	Art Unit	
	Shawn Hamidinia	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *3 and 9-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-8* is/are rejected.

7)☐ Claim(s) *1-3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-8, SEQ ID NO: 4 (domain A) and SEQ ID NO: 1, fragment 49-59 (domain B) in the reply filed on April 14, 2006 is acknowledged. The applicant's traversal is on the grounds that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinction between the identified groups or shown that a burden exists in searching all of the claims. This is not found persuasive because the restriction requirement clearly indicated that Group I and II do not possess a single general inventive concept. In the instant case, the special technical feature of Group I is a chloroplast targeting polypeptide as defined in SEQ ID NO: 4 or 5 and SEQ ID NO: 1 or 3. The special technical feature of Group II is a polynucleotide encoding a chloroplast targeting polypeptide, and nucleotide sequences and amino acid sequences are structurally distinct compounds which constitute different inventive concepts. Thus, the requirement is still deemed proper and is therefore made FINAL.

Priority

2. The current application filed on August 3, 2005 claims priority to French application 02/07729 filed on June 21, 2002.

Information Disclosure Statement

3. The information disclosure statement filed on December 17, 2004 has been considered. Please see the attached initialed PTO-1449.

Objections

4. Claims 1-3 are objected to because the claims read on non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112 and § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 6-7 provide for the use of an intraplastid-targeting polypeptide, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 6-7 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112-Enablement

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for polypeptides with 60% or 65% identity to SEQ ID NO: 4 or SEQ ID NO: 1, fragment 49-59. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Claims 6-8 are also rejected as being dependent from rejected claims 1-3 and failing to cure the defect.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404).

Factors to be considered in determining whether a disclosure would require undue experimentation include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is large because of the diverse variety of polypeptides that are encompassed within at least 60% or 65% sequence identity to SEQ ID NO: 4 or a fragment of SEQ ID NO 1 comprising amino acids 49-59. SEQ ID NO: 4 is a sequence that is 61 amino acids in length, hence, a polypeptide that has 60% identity allows for 40% of the polypeptide to vary which would be at least 24 residues. The number of changes this allows is astronomical (all 24 positions could be modified by 19 other amino acids alone or in any combination). In regards to a fragment of SEQ ID NO: 1, comprising amino acids 49-59, the term

"comprising" is open language which reads on the entire SEQ ID NO: 1 that has 329 amino acids. Hence, a polypeptide that has 60% or 65% identity to SEQ ID NO: 1 allows for 132 positions which could be modified by 19 other amino acids. (2) Also, there is no guidance provided by the specification on how to use the polypeptide which are 60% or 65% homologous to SEQ ID NO: 4 (domain A) or SEQ ID NO: 1, fragment 49 to 59. The specification does not describe how to determine if polypeptides with 60% or 65% homology to SEQ ID NO: 4 and SEQ ID NO: 1, fragment 49 to 59, still have functional activity, in particular, whether or not they retain their intraplastid-targeting properties. Further, (3) the specification is totally devoid of any working examples of intraplastid-targeting polypeptides which are more than 60% homologous to domain A or domain B. The specification merely characterizes the Arabidopsis IE41 protein and a small number of fragments of this sequence; As for the next Wands factor, (4) the nature of the invention is polypeptides having at least 60% or 65% sequence homology to SEQ ID NO: 4 and SEQ ID NO: 1, fragment 49 to 59. There is limited prior art (5) to the polypeptides of having more than 60% or 65% sequence homology to SEQ ID NO: 4 and SEQ ID NO: 1, fragment 49 to 59; (6) the relative level of skill in this art is very high; (7) the predictability of the art is low with regard to the determination of the function of any of these polypeptides and whether they intraplastid-targeting properties. Finally, (8) the claims are extremely broad because 60% sequence homology as claimed and all of the species of encompassed by this sequence identity are completely undefined and uncharacterized.

Based on this analysis, the conclusion that it would require undue experimentation to practice the instant invention is inescapable.

Claim Rejections - 35 USC § 112, First Paragraph-Written Description

10. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 6-8 are also rejected as being dependent from rejected claims 1-3 and failing to cure the defect.

The claims are drawn to an intraplastid-targeting polypeptide, which is defined as having an amino acid sequence that is at least 60% or 65% homologous to SEQ ID NO: 4 (domain A) and an amino acid sequence that is at least 60% or 65% homologous to a fragment of SEQ ID NO: 1 comprising amino acids 49 to 59. The claimed invention does not meet the current written description requirements for the following reasons. Firstly, substantial variation in structures and functions are expected among polypeptides that share 60% sequence identity to domain A and B. Therefore, the disclosure of the Arabidopsis IE41 protein does not provide adequate written description for all polypeptides having at least 60% or 65% sequence identity to domain A and B. Since Applicant does not have any representative examples of all the species of the polypeptides represented in claims 1-5, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms. Given this lack of

disclosure, Applicants' written description of the claimed invention is insufficient to show that Applicants were in possession of the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexandrov et al. (2000).

Alexandrov et al. teach a polypeptide sequence (SEQ ID NO: 49547) from Arabidopsis thaliana with 100% homology to SEQ ID NO: 4.

Alexandrov et al. further teach a polypeptide sequence (SEQ ID NO: 1332) from Arabidopsis thaliana with 100% homology to SEQ ID NO: 1, fragment 49-59.

Alexandrov et al. also teach a protein from Arabidopsis thaliana with 83.4% homology to the chimeric polypeptide which comprises domain B located at the N-terminal end of domain A.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawn Hamidinia whose telephone number is (571) 272-4534. The examiner can normally be reached on Mon-Fri from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SAH

ROBERT A. WAX
PRIMARY EXAMINER